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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/821,025	03/19/1997	HENDRIK LOUIS BIJL	246152006900	3574
25225	7590	02/17/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/821,025	BIJL ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The application should be reviewed for errors. As noted in the last Office action, error occurs, also in the recitation of “between... to” in claim 68. Generally, the accepted phrase is “between... and” or “from... to”. Correction is required. This criticism was not addressed.

The amendment filed 12/10/03 is acknowledged. Claims 68-95 are being considered on the merits.

The terminal disclaimer overcomes the double patenting rejection.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68-69, 76-80, 82, 84-87, 94-95 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barclay.

The claims are/remain directed to a granule composition comprising extruded microorganisms which are dead and non-disrupted and which are porous and have a diameter between 0.1 mm and 12 mm.

Barclay discloses a granule composition comprising extruded microorganisms, which are dead and non-disrupted. See, e.g., col. 12, lines 32-60. This granular composition is presumed to be inherently porous at least to some extent and to have a diameter between 0.1 mm and 12 mm. The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition, since it is prepared by the same process and is useful for the same purpose of providing omega-3 highly unsaturated fatty acids, for

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example, from unruptured cells by extraction (See, e.g., col. 13, lines 13-20). The process of extrusion inherently results in biomass that is porous, at least to some extent, since the material is disclosed as forming an “extruded matrix” (See, e.g., col. 12, line 47). Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to possess the same characteristics of the claimed composition particularly in view of the similar process of making by granules by extrusion of biomass and the property of allowing the extraction of fatty acids therefrom, for example, which they have been shown to share. Note the teachings of the reference regarding the various drying and extrusion processes (See, e.g., col. 12, lines 32-60). Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that spaghetti is an extruded food product that is not porous. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence. The way pasta is cut and dried has a tremendous effect on the finished product. The quality differences and ability of having sauces cling to the pasta come from the ingredients, the types of extruder, and the way the dough is handled. In addition, in the pet food industry, for example, most of the dry food is extruded and highly porous. In addition, extruded food products such as cheese and cereal puffs are porous extruded foods.. It should also be remembered that Barclay pertains to an extruded **matrix** which strongly suggests that the material is porous rather than solid, and it is used for animal food, which includes pet food, of course.

In response to the arguments that Barclay does not extract polyunsaturated fatty acids from the from the extruded product, it is noted that the claimed invention is not directed to an

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extraction process, but rather to a granular composition. Moreover, the product of Barclay comprises the fatty acid of interest, which can be obtained, if so desired. See, e.g., col. 12, lines 32-60. That Barclay chooses to disrupt the cells prior to extraction does not alter the nature of the composition disclosed or the fact that it reads on the claimed product. It is the Examiner's position that no distinction has been shown with objective evidence to distinguish the claimed product over the reference. Arguments directed to alleged differences in potential processes of use of the composition in the extraction of fatty acids do not demonstrate differences between the composition **as claimed** and the reference composition.

Therefore the rejection is deemed proper and it is adhered to.

Claims 68-95 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay taken with Carduck *et al.*, Akimoto *et al.*, Casey *et al.* and Remington *et al.*.

Barclay discloses a granule composition comprising extruded microorganisms, which are dead and non-disrupted. See, e.g., col. 12, lines 32-60. The referenced composition is prepared by the same process and is useful for the same purpose of providing omega-3 highly unsaturated fatty acids, for example, from unruptured cells by extraction (See, e.g., col. 13, lines 13-20). The process of extrusion results in a biomass that is granular and porous, as adequately demonstrated by Carduck (See, e.g., col. 4, last paragraph).

The references differ from the claimed invention in the nature of the microorganisms involved and in the presence of specific compounds in these microorganisms and may differ in the size of the particles or granules as well as the percentage of pores. However, Akimoto *et al.* adequately demonstrate that *Mortierella*, a yeast, is known to contain polyunsaturated fatty acids such as arachidonic acid which can be extracted with a solvent (See, e.g., Table 1). In addition, the reference discloses that *Aspergillus* is also a suitable source of compounds that can be extracted with a solvent. In addition, Casey *et al.* adequately demonstrate that *Pichia*, also a yeast, is known to contain tetraacetylsphingosine (TAPS) which can be extracted with a solvent (See, e.g., page 3, lines 32 et seq.).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Barclay by selecting another dried extruded microbial granular product containing dead microorganisms, such as further yeasts or fungi, including *Pichia* containing TAPS, as suggested by Casey *et al.* or *Mortierella* or

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Aspergillus as suggested by Akimoto *et al.* for the expected benefits of providing a valuable dried granular product that is porous and which is stable and easy to handle from which desired chemical compounds are extractable through the pores.

With respect to the specific content of dry matter and the specific sizes and percentage of porosity, it is apparent that these limitations are met by the composition of Barclay, but even if they are not, the selection of particle size is within the skill of the ordinary artisan in this art, as adequately demonstrated by Remington *et al.*. See, e.g., pages 1623-1627. In particular, the reference states that particle-size distribution can be controlled by varying the speed of rotation and drying temperature as well as by comminuting the granulation to the desired granule size after drying (page 1624, col. 2, last paragraph).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In *re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In *re* Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, all of the references are directed to the same subject matter comprising dried microbial granular products suitable as food and/or as a source for the extraction of proteins, lipids, vitamins, etc. from the microbial cells. It is noted that microbial cells include at least bacteria, yeasts, fungi and algae. It is noted that claim 68 is directed to "microorganisms".

Regarding Carduck, Applicant's argument that live and dead microorganisms are in "totally different fields" and that the person skilled in the art would not combine such references is puzzling. Carduck is relied upon to adequately demonstrate that porous granules are produced by extrusion having the correct dimensions. Whether the cells are alive or dead does not alter physical results of the process of extrusion of microbial cells, such as the presence of at least some porosity, as claimed.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more,

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weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). Two of the references in the instant case are relied upon to address specific claim limitations, i.e., Akimoto *et al.* to demonstrate that *Mortierella*, a yeast, is known to contain polyunsaturated fatty acids such as arachidonic acid which can be extracted with a solvent (See, e.g., Table 1) and that *Aspergillus* is also a suitable source of compounds that can be extracted with a solvent and Casey *et al.* to demonstrate that *Pichia*, also a yeast, is known to contain tetraacetylsphingosine (TAPS) which can be extracted with a solvent (See, e.g., page 3, lines 32 et seq.).

Applicant's arguments regarding the irrelevance of Remington are noted. This reference was cited to demonstrate that the selection of particle size is within the skill of the ordinary artisan in this art, and in particular, that particle-size distribution can be controlled by varying the speed of rotation and drying temperature as well as by comminuting the granulation to the desired granule size after drying (page 1624, col. 2, last paragraph). In this regard, Applicant argues a process of extruding cells, while the invention as claimed is directed to "A granule composition comprising extruded microorganisms" wherein the granules are porous and have a certain size range.

Applicant's arguments have failed to rebut the strong *prima facie* case of obviousness made out over the references. Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

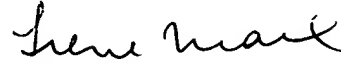
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 571-272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-9000.



Irene Marx
Primary Examiner
Art Unit 1651